Amendments to the Specification

Listed below is a marked-up copy of amended paragraphs of the Specification indicating the amended paragraphs of the Specification.

On page 5, please amend paragraph **[0011]** as follows:

[0011] Following coronary occlusion, successful acute reperefusion by thrombolysis, (clot dissolution) percutaneous angioplasty, or urgent surgery can decrease early mortality by reducing arrhythmias and cardiogenic shock. It is also known that addressing ischemic cardiomyopathy in the acute phase, for example with reperfusion, may salvage the epicardial surface. Although the myocardium may be rendered akinetic, at least it is not dyskinetic. Post-infarction surgical re-vascularation can be directed at remote viable muscle to reduce ischemia. However, it does not address the anatomical consequences of the akinetic region of the heart that is scarred. Despite these techniques for monitoring ischemia, cardiac dilation and subsequent heart failure continue to occur in approximately 50 percent of post-infraction patients discharged from the hospital.

On page 6, please amend paragraph **[0015]** as follows:

[0015] In response to these and other problems, an improved apparatus and method is provided for restoring the geometry of the left ventricle to counteract the effects of cardiac remodeling. One embodiment of the present invention provides an apparatus and method to reconstruct an enlarged left ventricle of a human heart, using a shaper, having a size and shape substantially equal to the size and shape of an appropriate left ventricle, wherein the shaper is adapted to be temporarily placed into the enlarged left ventricle during a surgical procedure. Another aspect of one embodiment comprises a ventricular patch adapted for placement into the left ventricle of a heart made from a sheet of biocompatible material, and having a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch. In another aspect of one embodiment, a device is presented, comprising ~~of~~ a handle and a sizing template adapted to be coupled to the handle. Such components are also

presented as a kit for use during ventricular restoration surgery.

On page 8, please amend paragraph **[0045]** as follows:

[0045] Turning to Fig. 1, there is presented an overview method 100 for performing and using one embodiment of the present invention. A more complete discussion of this method will be presented below. The method 100 may use the following components: a shaping device 200 (Fig. 2a), a patch 300 (Fig. 3a), a sizer 402a (Fig. 4a), and a suture hook 520 (Fig. 5b). Referring back to Fig. 1, at step 102, a surgeon determines the appropriate size for the patient's left ventricle based on the patient's height, weight, body surface area and other patient specific conditions. Once the patient's appropriate ventricle size has been determined, at step 104, the surgeon can then select the appropriate volume for the shaping device 200. At step 106, the surgeon opens up the chest cavity in a conventional manner. An incision is cut into the myocardial wall of an enlarged heart in step 108. At step 110, non-viable tissue is identified. At step 112, the surgeon may remove all or some of the non-viable tissue (i.e., the dyskinetic and akinetic areas) of the myocardium. A continuous round stitch, known in the art as a Fontan stitch, may then be woven into the ventricle, at step 114. The stitch produces an annular protrusion, which forms an opening. At step 116, the shaping device 200 may be inserted into the ventricle through this opening. The musculature of the myocardium may be pulled over the shaping device to form a left ventricle having a predetermined volume, shape and contour. The shaping device 200 may then be compressed and removed at step 120. At step 122, with the aid of the sizer 402a, the surgeon may determine the preferred location of and size of the patch 300 which may be placed in the left ventricle. The patch 300 is then cut to size in step 124 and secured to the inside of the myocardium in step 126. At step 128, with the patch 300 suitably placed, the ventricle is closed by joining the myocardial walls over the patch.

On page 11, please amend paragraph **[0051]** as follows:

[0051] In some embodiments, such as illustrated in Fig. 2b, the shaping device may be an inflatable balloon 201, having a thickness of in the range of .02 to .08 inches, preferably .03 inches. A distal end of a filler tube 208 may be coupled to a point 207 along the exterior surface

of balloon 201. For instance, the point 207 could be located approximately 1/3 along balloon's 201 length, as illustrated in Fig. 2b. In other embodiments, the filler tube 208 may be coupled to vertex 206. Such tubes are well known in the art, and illustratively may be made of materials such as PVC. A proximal end of the filler tube 208 may be connected to a fluid reservoir, such as a syringe 210 which may inject a pre-specified amount of fluid into the balloon 201 through the filler tube 208. Also coupled to the distal end of the filler tube 208 may be a fluid control device such a stopcock 212. The injection of fluid through the filler tube 208 inflates the balloon 201 to an inflated condition, as illustrated in Fig. 2b. Once inflated, the fluid inside the shaping device may be prevented from escaping by locking the stopcock 212. This allows the balloon 201 to stay inflated with the proper volume, shape and contour during the reconstruction procedure.

On page 14, please amend paragraph **[0061]** as follows:

[0061] The shaping device 280 illustrated in Fig. 2g is in an expanded condition. Running through the center of shaping device 280 is a main shaft 282. The main shaft 282 has a distal end 284 and a proximal end 286. At the distal end 284 is a joint 288. Coupled to the joint 288 is a series of back ribs 290a though 290h (only back ribs 290a through 290e are visible in Fig. 2g). Back ribs 290a through 290h are connected to front ribs 292a-292h by hinges 294a though 294h (only front ribs 292a-292e and hinges 294a-294e are visible in Fig. ~~2f~~2g). The proximal end of front ribs 292a through 292e are connected to a collar 296 through a series of hinges (not shown) radially spaced around collar 296. The use of hinges around collar 296 encourages front ribs 292a-292h to form a convex angle with respect to shaft 282 at collar 296.

On page 14, please amend paragraph **[0062]** as follows:

[0062] Fig. 2h shows the shaping device 280 in a collapsed position. In a collapsed position, back ribs 290a-290h and front ribs 292a-292h surround shaft 282 as illustrated in Fig. 2j. Fig. 2j is a section view cut transversely through shaft 282 and the front ribs 292a-292h. In operation, once the shaping device 280 is inserted into the left ventricle, a surgeon may slide collar 296 along shaft 282 towards distal end 284. The force exerted on collar 296 will cause the ribs to buckle radially outward as illustrated in Fig. 2g. Eventually, the front ribs 292a-292h will bend

under the applied force. Because the front ribs 292a-292h are under stress, they will tend to push the collar 296 towards proximal end 286. A lock 294 prevents ~~any desired~~ movement towards proximal end 286. Thus, the collar 296 is held firmly in place along shaft 282 by the front ribs 292a-292h exerting a force through collar 296 to lock 294. The lock 294 is spring (not shown) activated and is designed such that the collar 296 may easily slide over the lock when moving from the proximal end 286 to the distal end 288. When the surgeon is ready to remove the shaping device 280, the surgeon may collapse the shaping device 280 by pressing down on lock 294 which will allow the collar 296 to slide past the lock 294 towards the proximal end 286.

On page 17, please amend paragraph **[0072]** as follows:

[0072] Turning now to Fig. 4a, there is illustrated a set of sizers 402a-402d. The sizers 402a-402d are shaped to be the approximate size of the patch 300 (Fig. 3a). Similar to the patch, the sizers 402a-402d will be of various geometries, length and width combinations. For illustrative purposes, the sizers 402a-402d discussed herein will be elliptical in shape. For posterior repairs to the ventricle, however, the sizers may have a general triangular shape. Referring back to Fig. 4a, the length of the sizers along a major axis 403 may be in the range of 2 to 7 cm in length. The length along a minor axis 405 may be 1 to 5 cm in length. The sizers may have a connection 406 for attachment to a handle 404 (Fig. 4b). The sizers 402a-402d can be made out of plastic or stainless steel or any rigid material. Four sizers 402a-402d are illustrated in Fig. 4a, however, any number of sizers in a variety of shapes could be provided.

On page 18, please amend paragraph **[0075]** as follows:

[0075] In another embodiment, the sizers may have a cutting edge which can be used to cut the patch 300 to the appropriate shape. Turning now to Fig. 4d, a sizer 430 is shown connected to the handle 408. In this embodiment, the sizer 430 may have a ridge 432 concentric to the shape of the sizer 430. The ridge 432 allows a surgeon to accurately estimate the size of the opening by placing the ridge 432 into the opening. The sizer 430 may also have a circumferential flange or lip 434 around the perimeter of the sizer to assist in defining the patch size. The patch will typically be slightly larger than the size of the opening. The width of the lip 434 will preferably

have a constant width around its circumference, typically in the range between 5 and 8 centimeters. A cutting edge 434' may also be coupled to the perimeter of the lip. In operation, the surgeon may use the sizer as illustrated in Fig. 4d to estimate the size of the opening, remove the sizer 430 from the handle 408, turn the sizer 430 over with respect to the handle 408, and re-attach the sizer 430 to the handle 408. The cutting edge 434' may then be used to cut the patch material to the correct size and shape by pressing the cutting edge into the patch material.

On page 20, please amend paragraph **[0081]** as follows:

[0081] In yet another embodiment of the present invention, a kit 600 for surgically reshaping the left ventricle of the heart is illustrated in Fig. 6. The kit 600 may include any of the components discussed above, including: the balloon 201 coupled to the syringe 210, a set of the sizers 402a-402d in various shapes and sizes, a handle 404 to attach to the sizers ~~402a-402d~~402, material 602 for creating the patch 300 (not shown), the suture hook 520 and, the patch holder 500 (not shown). The components of the kit 600 may be packaged in a sterile manner as known in the relevant art.

On page 22, please amend paragraph **[0089]** as follows:

[0089] In step 714, the preferred location of the patch 300 is ~~been~~ determined relative to the circumferential line. In step 716, a continuous Fontan stitch may be placed in proximity to the line, along the long axis of the heart. The Fontan stitch produces an annular protrusion, which forms a neck relative to the circumferential line. The annular protrusion may be further defined by placing a rim support around its perimeter. This neck initially may have a round circular configuration. A second Fontan stitch may be placed 90 degrees from the initial stitch along the short axis of the heart. Other stitches may be placed as needed to form the heart to the shaping device. The stitch will serve to shape the heart along the short axis of the heart if needed.

On page 22, please amend paragraph **[0090]** as follows:

[0090] In step 718, the shaping device 200 may then be inserted into the ventricle. The shaping device 200 is then inflated or expanded, the volume of which is equivalent to the appropriate volume of the ventricle for the patient. The shaping device 200 provides the model upon which the ventricle can be shaped and contoured through the use of the Fontan suture in step 720. The Fontan suture may then be tightened with the aid of the suture hook 520, in step 722. As the suture or sutures are tightened, the musculature of the myocardium will form the physiologically correct volume, shape and contour over the shaping device. The appropriately oval-shaped opening in the neck defines the area where the patch will be placed. Once the suture is tightened down, the shaping device 200 may be collapsed and removed in step 724.

On page 23, please amend paragraph **[0095]** as follows:

[0095] When air evacuation is confirmed by transesophageal echo, the patient can be weaned off bypass usually with minimal, if any inotropic support. ~~Decannulasation~~ Decannulisation may be accomplished with conventional methods (step 736).